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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,298	11/21/2003	Navroz Boghani	261088US0	2138

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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	**PAPER NUMBER**
1616	

NOTIFICATION DATE	DELIVERY MODE
04/14/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/719,298	BOGHANI ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37,47,64-70 and 88-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37,47,64-70 and 88-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Nathan Schlientz can be reached at 571-272-9924.

Status of Claims

Claims 1-37, 47, 64-70 and 88-98 are pending in the present application and examined herein on the merits for patentability. No claim is allowed at this time.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 26 January 2009 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Terminal Disclaimer

The terminal disclaimer filed on 11 June 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on U.S. Patent Application Nos. 11/134,356, 11/134,365, 11/134,367, 11/134,370, 11/134,371, 11/134,480 and 11/135,153 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

Applicant's arguments filed on 26 January 2009 have been fully considered but they are not persuasive, as discussed herein below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claims 3 and 4 recite, "The delivery system of claim 1 wherein *the edible composition* is selected…" However, claims 3 and 4 are dependent from claim 1 which does not recite "edible composition". There is insufficient antecedent basis for this limitation in the claims.

2. Claim 70 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claim 70 recites, "The edible composition of claim 66 wherein *each of the at least two delivery systems* has a different tensile strength." However, claim 70 is dependent from claim 66, which is dependent from claim 1, neither of which require "at least two delivery systems". Claim 1 is drawn to a delivery system, and claim 66 is drawn to the delivery system of claim 1. There is insufficient antecedent basis for this limitation in the claims. It is believed by the

examiner that Applicants intended claim 70 to be dependent upon claim 67, which requires at least two delivery systems.

3. Claims 93-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claims 93-95 recite a tensile strength modifying agent present is a percentage range, but do not recite what the percent is with respect to. In other words, it is not clear if the percent values of claims 93-95 are percents by weight, which would be consistent with the previous claims and the specification, or if the percents are by volume, w/v, v/v, etc. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 8, 18, 21, 22, 47, 64-67 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitajima et al. (US 3,691,090).

Kitajima et al. teach a process for the preparation of capsules containing a core material and an encapsulating material (col. 1, lines 39-41). Column 2, lines 8-15 teaches that the core material selected from foods, enzymes, medicines, etc. Column

2, lines 20-26 teach examples of the encapsulating material of which ethylcellulose, and polyvinyl acetate are mentioned. Example 3 teaches a method of making aspirin containing capsules, wherein ethylcellulose is the encapsulating material. Kitajima et al. is silent with respect to the tensile strength of the particle. Tensile strength of the particle depends on the encapsulating material used. Since Kitajima et al. teach the claimed encapsulating material the limitation of tensile strength of the particle will be inherent.

Response to Arguments

Applicants argue on page 13 that under the conditions Kitajima et al. describe for removing the solvent after dispersion, no matter how hard one tries there will be a remaining solvent residue in the end product capsules, and thus the Kitajima et al. compositions are not free of solvents. However, the examiner respectfully argues that Kitajima et al. repeatedly disclose that the organic solvent is evaporated away (col. 1, ln. 45-46; col. 3, ln. 49-50 and 59-63; col. 5, ln. 19-21; and claims 1, 7 and 10). Therefore, Kitajima et al. disclose that the final product does not comprise an organic solvent.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP 716.01(c)(II).

2. Claims 1-37, 47, 64-70 and 88-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Schobel et al. (US 4,824,681).

Schobel et al. disclose an encapsulated sweetener (abstract). Column 5, line 55 through column 6, line 10 teach the sweetening agents which can be used in the invention. A particularly preferred sweetening composition is prepared when the encapsulated sweetener is aspartame and the sweetener in the coating material is saccharin (col. 7, ln. 67 through col. 8, ln. 20). This combination is known to act synergistically to enhance sweetness. The coating material may further comprise a nontoxic water soluble acidifying agent. The acidifying acid will act as a flavor enhancer or flavorant. In addition, the acidifying agent has been unexpectedly found to stabilize dipeptide sweeteners such as aspartame. This unexpected increased stabilization has permitted the preparation of chewing gum compositions sweetened with aspartame to have a stable shelf life greater than one year and to have a sustained sweetness release lasting up to 30 minutes. Acidifying agents suitable for use in the present invention include but are not limited to citric acid, tartaric acid, malic acid, ascorbic acid, sorbic acid, lactic acid, fumaric acid, acesulfame, saccharin and mixtures thereof. A particularly preferred acidifying agent is saccharin. Saccharin has the ability to both acidify and sweeten.

Column 6, lines 25-28 teach the particles size from about 150 to 300 microns. Column 7, lines 12-41 teaches that the coating material comprises a hydrophobic polymer and a hydrophobic plasticizer, wherein the polymer can be polyvinyl acetate phthalate and the polymer is about 55% to about 95% of the coating material. Example

1 teaches a method of making encapsulated high intensity sweetener aspartame, wherein the particles contain from 94.3% to 96.2% of the sweetener. Examples 3-6 teach a chewing gum comprising from about 1.7 to 2.7% of the encapsulated material together with additional flavoring agents. Schobel et al. is silent with respect to the tensile strength of the particle. Tensile strength of the particle depends on the encapsulating material used. Since Schobel et al. teach the claimed encapsulating material, the limitation of tensile strength of the particle will be inherent.

Response to Arguments

Applicants argue on page 15 that in Schobel et al., the residual solvent remains and therefore the compositions are not free of solvents. However, the examiner respectfully argues that Schobel et al. disclose in Example 1 that the dry weight of IA and IB does not comprise any ethanol or water (col. 10, ln. 55-65). The aspartame granules are then coated (col. 10, ln. 66 through col. 11, ln. 29), where the coated particles pass out of an upward stream and pass downward in a fluidized condition countercurrent to a flow of heated fluidized gas whereupon they are dried (col. 9, ln. 4-9). Therefore, Schobel et al. disclose that the final product is dried and thus does not comprise a solvent.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the

date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP 716.01(c)(II).

Applicants further argue on page 15 that Schobel et al. do not disclose the inclusion of a tensile strength modifying agent. However, the examiner respectfully argues that Schobel et al. disclose inclusion of a plasticizer. The instant specification defines tensile strength modifiers as including plasticizers, also referred to as softeners (pg. 19, ln. 2, 4 and 8-9; and pg. 22, ln. 9-12). Therefore, the plasticizer of Schobel et al. read on "tensile strength modifying agent" within the present claims.

3. Claims 1, 2, 5, 8, 18, 47, 64-66 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardner et al. (US 3,341,416).

Gardner et al. disclose encapsulation of aspirin in ethyl cellulose and its products (Title and col. 1, ln. 11-12). Gardner et al. disclose micro-encapsulation of tiny particles of aspirin, each particle entity being confined and protected in a wall of ethyl cellulose (col. 1, ln. 21-23). Gardner et al. further disclose dissolving ethyl cellulose and polyethylene in cyclohexane at 80 °C, addition of aspirin of specified particulate size, cooling to room temperature over 2 hours, and recovery of the ethyl cellulose coated aspirin particles by filtering and hardened by further drying of the cyclohexane therefrom (Example I). Gardner et al. disclose varying ratios of aspirin to ethyl cellulose (col. 1, ln. 64 through col. 2, ln. 1; and Examples I-III), as well as varying the aspirin particle size (Example IV).

4. Claims 1-37, 47, 64-70 and 88-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang (US 4,711,784).

Yang discloses encapsulating an active ingredient, such as the artificial sweetener aspartame, with a high molecular weight polyvinyl acetate blended with a hydrophobic plasticizer in the absence of an added solvent, wherein the encapsulated active ingredient can then be used in a composition for ingestion by a human, such as in the form of a chewing gum (Abstract; and col. 4, ln. 11-17). Yang discloses that the active ingredient can include sweeteners, dietary fiber, flavoring agents and bio-effecting agents (col. 4, ln. 32-38). Yang discloses that sweeteners include amino acid based sweeteners, dipeptide sweeteners, especially aspartame, glycyrrhizin, saccharin and its salts, acesulfame salts, cyclamates, steviosides, talin, dihydrochalcone compounds and mixtures thereof (col. 4, ln. 42-47), wherein a particularly effective combination of sweeteners has been found to be aspartame in combination with saccharin which can be prepared in the encapsulating composition in such a manner that they can be released over a period of time either simultaneously or sequentially (col. 8, ln. 3-8). The solid product is usually ground sufficiently to enable the particulate to pass through a 30 mesh sieve (i.e., less than 600 μm) (col. 9, ln. 14-16).

Yang specifically discloses examples wherein 9% aspartame or saccharin are encapsulated in 36 or 64% polyvinyl acetate and 55 or 27% glyceryl monostearate (Examples 3 and 4), wherein the encapsulated sweeteners were made into chewing gum products comprising gum base, triacetin, vegetable oil, sugar, sorbitol, peppermint oil and the encapsulated sweetener (Table I).

It is noted by the examiner that Yang is silent with respect to the tensile strength of the granulated sweetener encapsulated in the polyvinyl acetate and plasticizer. However, tensile strength of the particle depends on the encapsulating material used. Since Yang discloses the claimed encapsulating material, the limitation of tensile strength of the particle will be inherent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-37, 47, 64-70 and 88-92 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37, 47, 63-70 and 88-91 of copending Application No. 11/083,968. Although the conflicting claims are not identical, they are not patentably distinct from each other

because both copending applications claim a delivery system comprising a least one active component encapsulated within an encapsulating material. The difference between the two is the minimal tensile strength of the system. In the instant invention the tensile strength is at least 10,000 psi and the copending application has a tensile strength of at least 6,500 psi. Because the copending broadly discloses the same range as the instant invention it is obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants do not argue this rejection in their response filed 26 January 2009. As a result, the examiner maintains the rejection.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616